CLAIMS

1. Aerosol composition comprising a propellant and contained therein a first particulate material comprising particles having a median aerodynamic diameter within the range 0.05 to 11 μm and a second particulate material comprising particles having a median volume diameter within the range 15 to 200 μm.

2. Composition according to claim 1 wherein the second particulate material has a median volume diameter within the range 20 to 125 μm, preferably within the range 25 to 125 μm, more preferably within the range of 38 to 125 μm, even more preferably within the range 45 to 125 μm and even more preferably within the range of 63 to 125 μm.

3. Composition according to any one of the preceding claims wherein the weight ratio of first particulate material to second particulate material in the composition lies in the range 1:0.1 to 1:500.

4. Composition according to claim 3 wherein the weight ratio of first particulate material to second particulate material in the composition lies in the range 1:10 to 1:100, preferably in the range 1:25 to 1:67.

5. Composition according to claim 1 wherein the first particulate material has a median aerodynamic diameter within the range 1 to 10 μm, preferably within the range 1 to 5 μm.

6. Composition according to any one of the preceding claims wherein the second particulate material has a Mohs hardness value of less than 6.5, preferably less than 5, even more preferably less than 4 and even more preferably less than 3.

7. Composition according to any one of the preceding claims wherein the second particulate material has a Carr Index value:

for particles more than 100 μm in size of less than 14%. preferably less than 12%, even more preferably less than 10%;

for particles less than 100 μm in size of less than 28%, preferably less than 26%, even more preferably less than 24%;

for particles less than 40 μm in size of less than 35%, preferably less than 33%, even more preferably less than 31%; and

for particles less than 20 μm is size of less than 65%, more preferably less than 63%, even more preferably less than 61%.

8. Composition according to any one of the preceding claims wherein the solubility of the first particulate material in the propellant is less than 49.9wt% with respect to the total weight of the substance present in the composition comprising the first particulate material present, preferably less 10 wt%, more preferably less than 1.0 wt%.

9. Composition according to any one of the preceding claims wherein the solubility of the second particulate material in the propellant is less than 49.9 wt% with respect to the total weight of the substance present in the composition comprising the second particulate material, preferably less than 10 wt%, more preferably less than 1.0 wt%.

10. Composition according to any one of the preceding claims wherein the composition comprises at least 80 wt% and up to 99.999 wt% propellant, more preferably at least 90 wt% and up to 99.9 wt% propellant.

11. Composition according to any one of the preceding claims wherein the composition comprises at least 0.001 wt% and up to 20 wt% of the total of first and second particulate material present, preferably at least 0.1 wt% and up to 10 wt% of the total of first and second particulate material present.

12. Composition according to any one of the preceding claims further comprising a surfactant, flavouring material. buffer, preservative or any mixture thereof.

13. Composition according to any one of the preceding claims wherein the propellant is selected from chlorofluorocarbons, hydrofluorocarbons and mixtures thereof.

14. Composition according to any one of the preceding claims wherein the propellant is selected from hydrofluorocarbons and mixtures thereof.

15. Composition according to claim 14 wherein the propellant is a hydrofluoroalkane selected from the 1,1,1,2-tetrafluoroethane, 1,1,1,2,3,3,3-heptafluoropropane and mixtures thereof.

16. Composition according to any one of the preceding claims wherein the second particulate material is selected from carbohydrates including sugars, mono-, di-, tri-, oligo-, poly- saccharides, and any physiologically acceptable derivatives, salts, forms and solvates thereof, and any mixtures thereof.

17. Composition according to any one of the preceding claims wherein the second particulate material is selected from amino acids, di-, tri-, oligo-, polypeptides, proteins and any physiologically acceptable derivatives, salts, forms and solvates thereof and mixtures thereof.

18. Composition according to any one of the preceding claims wherein the first particulate material is a medicament.

19. Composition according to claim 18 wherein the medicament is selected from salbutamol, salbutamol sulphate, terbutaline, terbutaline sulphate, ipratropium bromide or any physiologically acceptable salts or solvates thereof; beclomethasone diproprionate, budesonide, triamcinolone acetonide or any physiologically acceptable solvates thereof; corticosteroid, bronchodilator; peptides, proteins, nucleic acids or derivatives thereof; insulin, calcitonin, growth hormone, lutenising hormone releasing hormone, leuprolide, oxytocin or any physiologically acceptable salts or solvates thereof, or any mixture thereof.

20. Composition according to claim 18 wherein the medicament is salmeterol xinafoate, or any mixture thereof with any medicament according to claim 19.

21. Composition according to claim 18 or 19 wherein the medicament is salbutamol sulphate.

22. Composition according to claim 18 wherein the medicament is fluticasone propianate, or any mixture thereof with any medicament according to claim 19.

23. Composition according to claim 18 or 19 wherein the medicament is beclomethasone dipropionate or a physiologically acceptable solvate thereof, or any mixture thereof with any medicament according to claim 19.

24. Pharmaceutical composition comprising a propellant and contained therein a particulate medicament comprising particles having a median aerodynamic diameter within the range 0.05 to 11 μm and a second particulate material comprising particles having a median volume diameter within the range 15 to 200 μm.

25. A container containing a composition according to any one of the preceding claims wherein the container includes a valve outlet.

26. A container according to claim 18 wherein the valve outlet is a metered dose valve.

27. An inhalation device incorporating a container according to claim 25 or claim 26.

28. A container according to claim 26 in the form of a metered dose inhaler.

29. A method for preparing an aerosol composition according to any one of claims 1 to 24 comprising:-

(a) forming a mixture of the first particulate material and the second particulate material;

(b) dispensing measured portions of respectively the said mixture and the propellant into a container; and

(c) sealing the container.

30. The method according to claim 29 wherein the mixture is dispensed into the container before the propellant.

31. A method for preparing an aerosol composition according to any one of claims 1 to 24 comprising admixing the ingredients together prior to dispensing into a container and sealing the container.

32. The method according to any one of claims 29 to 31 wherein the container includes an outlet valve, preferably a metered dose valve.

33. A mixture of a first particulate material having a median aerodynamic diameter within the range 0.05 to 11 μm and a second particulate material having a median volume diameter within the range 15 to 200 μm.

34. A method of administering a particulate medicament to a patient in need thereof comprising forming an aerosol from the aerosol composition according to any one of claims 18 to 24 and the patient inhaling the aerosol.

35. An aerosol composition according to any one of claims 18 to 24 for use in the treatment of respiratory disorders.